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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/658,118	09/09/2003	Stephen P. Horstmann	E-2114	9685

7590 11/20/2006

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EXAMINER

ALTSCHUL, AMBER L

ART UNIT	PAPER NUMBER
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3626

DATE MAILED: 11/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	Application No. 10/658,118	Applicant(s) HORSTMANN, STEPHEN P.	
	Examiner Amber L. Altschul	Art Unit 3626	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 September 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>12/27/2004</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. Claims 1-5 have been presented for examination.

#### ***Drawings***

2. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because Figs 1-10 contain informal handwritten text and shading that may affect clarity once reproduced. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

#### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by United States Patent Application Publication Number US 2002/0072933, Vonk, et al., hereinafter Vonk. (Reference A on the attached PTO-892).

5. As per claim 1, Vonk teaches an apparatus for managing clinical studies to facilitate the tracking of the studies by personnel involved in the study, such as managers and coordinators, wherever they are located (abstract), i.e. a plurality of remote monitoring stations and a computer network. Each of the remote monitoring

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stations includes at least one measuring device, adapted to measure a physiological condition of a respective patient, and to provide data representative of the physiological condition for inclusion among patient health-related data pertaining to a respective patient; as well as placing orders, (p. 4, Paragraphs 46-47), i.e. The workstation 114 also enables such information to be communicated from the client 112 to centralized database 104 which provide services to a care team in charge of monitoring the client 112. Patient education may be "prescribed" through the healthcare network by a member of the care team or obtained through patient self-exploration using a home information appliance (interactive television, pager, wireless phone, handheld device), and the clients 112 are also each provided with monitoring or diagnostic tools, such as blood pressure measuring devices 116, electronic scales 118, and disease management information charts 120, as well as glucometers, thermometers, spirometers, medication management and various other devices which can be used to obtain diagnostic and assessment information from the clients 112; and receiving financial information, (abstract), i.e. is adapted to receive financial data pertaining to the treatment programs; comprising processor means for processing information, (page 1, para. 4), i.e. Meta-services aggregate data from local networks, process the data; data storage means for storing data which is associated with the processor means (abstract), i.e. to store the financial data in the database; software for providing instructions to control the processor means, (page 12, para. 117), i.e. the network 100 provides software tools, devices, protocols, computers, and data networks; and a communications link for permitting from a location remote from the data storage means

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one or the other or both of access to information stored in the data storage means and retrieval of information stored on the data storage means, (page 11, para. 112), i.e. Web technology and the Internet permits asynchronous communications between clients 112 and individual providers; wherein the apparatus further comprises discrimination means for discriminating between users who have been assigned different levels of access, (page 3, para. 30), i.e. the centralized network communicates via the Internet, for example, to workstations that can be used by care managers, and workstations that can be used by care providers, such as physicians and specialized healthcare providers, so that the managers and providers can readily add and retrieve information to and from the database. The centralized network also communicates via the Internet, for example, to one or more IDNs or other payors. Therefore, the system is being accessed by a plurality of users who are accessing the system on different levels.

6. As per claim 2, Vonk teaches a method for managing clinical studies to facilitate the tracking of the studies by personnel involved in the study, such as managers and coordinators, wherever they are located, (abstract), i.e. a plurality of remote monitoring stations and a computer network. Each of the remote monitoring stations includes at least one measuring device, adapted to measure a physiological condition of a respective patient, and to provide data representative of the physiological condition for inclusion among patient health-related data pertaining to a respective patient; as well as placing orders, (p. 4, Paragraphs 46-47), i.e. The workstation 114 also enables such information to be communicated from the client 112 to centralized database 104 which provide services to a care team in charge of monitoring the client 112. Patient education

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may be "prescribed" through the healthcare network by a member of the care team or obtained through patient self-exploration using a home information appliance (interactive television, pager, wireless phone, handheld device), and the clients 112 are also each provided with monitoring or diagnostic tools, such as blood pressure measuring devices 116, electronic scales 118, and disease management information charts 120, as well as glucometers, thermometers, spirometers, medication management and various other devices which can be used to obtain diagnostic and assessment information from the clients 112; and receiving financial information, (abstract), i.e. is adapted to receive financial data pertaining to the treatment programs; comprising the steps of processing with processor means for processing data stored in a data storage means for storing data which is associated with the processor means, (page 1, para. 4), i.e. Meta-services aggregate data from local networks, process the data and (p.3, para. 29), i.e. The network includes a centralized network comprising, for example, a computer or computer network, and a centralized database for storing information pertaining to the healthcare management network, such as patient information, treatment plan information, recommendations from care providers, recommendations from healthcare managers, and so on; and providing software for providing instructions to control the processor means, (page 12, para. 117), i.e. the network 100 provides software tools, devices, protocols, computers, and data networks; and exchanging information through a communications link, (page 11, para. 112), i.e. Web technology and the Internet permits asynchronous communications between clients 112 and individual providers; and monitoring the status of one or more

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steps of a clinical study, (page 2, para. 16), i.e. to provide this monitoring using remote devices and a data network to transfer information about patient status to the providers.

7. Regarding claim 3, Vonk teaches a system for managing clinical studies, comprising assigning a project management task as one of a component task and work order based task, (p.5, para. 48), i.e. Tools are also provided to assist providers as they respond to this patient information including resource management, scheduling, guidelines, protocols, and behavioral tools, tracking the status of the task through completion of the task, (p. 8, para. 78), i.e. the healthcare manager reviews the data from the client 112 regularly, evaluates whether the data is consistent with expected outcomes, and communicates with the client 112 regarding inconsistent outcomes, storing information about the task on a data storage device, (p.5, para. 48), i.e. Client information is then archived into a second database for further analysis to benchmark performance and identify opportunities for improvement of care practices, providing access means for users to access the data stored on the data storage device to display information about the task, (p.8, para. 77), i.e. During this time, the centralized network 102 is receiving input of the data and using preset parameters to determine if the data is outside normal limits. The centralized network 102 notifies the healthcare manager of the data that is outside the limits, and receives, stores and tracks the data provided by the client 112. At all times, customer services and support can be provided as necessary.

8. Regarding claim 4, Vonk teaches a method for managing clinical trial studies, comprising the steps of: providing a processor, (p.8, para. 82), i.e. The centralized

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network 102 provides the data necessary to perform these evaluations to the healthcare manager and the designated primary care team members and provide support for additional data process analysis, providing software to control the processor so that a plurality of users may collaborate on the same document, (p.8, para. 82), i.e. the aggregate report data can be reviewed for improvements. The advisory board can consider the improvement suggestions and provide a recommendation for a pertinent plan of action, collaborating on a document including reviewing and annotating the document with the user's comments, (p. 8, para. 82), i.e. the improvements are incorporated into the network as well as into the generic standards of care that have been predeveloped and are shown in the activities box labeled 1450, tracking the status of the document by associating the collaboration status with the project status, (p.9, para. 84), i.e. the healthcare manager will monitor the status of the clients 112 he or she is managing.

9. Regarding claim 5, Vonk teaches a method for managing clinical trial studies comprising the steps of storing information associated with clinical study documentation, (p. 4, para. 43), i.e. As illustrated, the network 100 includes a centralized computer or computer network 102 including a centralized database 104 for storing information pertaining to patients in the network, as well as healthcare and health outcomes information. The network 100 is preferably an Internet-based network which enables parties participating in the network 100 to access the centralized database 104 via the internet, providing a real-time status of clinical trial study documentation for a plurality of users accessing the information, (p.12, para. 113), where a change to the

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documentation by an authorized user is made available to one or more other authorized users (p.4, para. 44), i.e. network 100 can include any suitable number of care teams, and each care team can include any suitable number of managers, a primary care team and extended care teams. The members of the care team 106 have access to workstations, such as personal computers, handheld devices, pagers, wireless phones or the like, which can interact with the centralized network 102 via the Internet 108 to access data in the centralized database 104 and to provide data to the centralized database 104 as described in more detail below, the method including maintaining the progress status for tasks relating to the clinical trial study documentation, (p.5, para. 53), i.e. the healthcare managers review the status of their respective clients 112 and compare their client's progress to expected outcomes.

### **Conclusion**

10. Any inquiry concerning this communication or earlier communications from the examiner concerning this communication or earlier communications from the examiner should be directed to Amber Lee Altschul whose telephone number (571) 270-1362. The examiner can normally be reached Monday thru Thursday 7:30-5 and every other Friday 7:30-4.

11. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patrick Nolan, Ph.D., can be reached at (571) 272-0847. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-1035.

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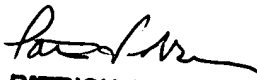
12. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amber Lee Altschul

Patent Examiner

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pn

  
PATRICK J. NOLAN, PH.D.  
SUPERVISORY PATENT EXAMINER

11/8/06